## **AMENDMENTS TO THE CLAIMS**

## IN THE CLAIMS

Please amend the claims as follows:

Claims 1-26 (cancelled).

- 27. (currently amended) Leflunomide, prepared by a process comprising the steps of:
  - a) providing 5-methylisoxazole-4-carboxylic acid chloride; and
  - b) contacting the 5-methylisoxazole-4-carboxylic acid chloride with 4-trifluoromethylaniline in the presence of an alkali metal or alkaline-earth metal bicarbonate in an acylation solvent system comprising at least one solvent component selected from the group consisting of water, ethyl acetate, toluene and dimethyl acetamide; and
  - c) isolating the leflunomide, wherein the leflunomide has about 150 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 28. (currently amended) The leflunomide of claim 27 wherein 5-methylisoxazole-4-carboxylic acid chloride is provided as crude 5-methylisoxazole-4-carboxylic acid or a residue by:
  - a) chlorinating 5-methylisoxazole-4-carboxylic acid by contacting it with a chlorinating agent to form crude 5-methylisoxazole-4-carboxylic acid chloride; and
  - b) optionally evaporating excess chlorinating agent or volatile byproducts of the chlorination under reduced pressure, whereby the evaporation leaves a residue of unevaporated material containing 5-methylisoxazole-4-carboxylic acid chloride.
  - 29. (cancelled)
  - 30. (cancelled)
- 31. (currently amended) The leflunomide of claim 30 27 containing about 100 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 32. (original) The leflunomide of claim 31 containing about 50 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 33. (original) The leflunomide of claim 32 containing about 10 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 34. (original) The leflunomide of claim 27 which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide.

- 35. (original) The leflunomide of claim 27 which is substantially free of N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.
- 36. (currently amended) The leflunomide of claim 27 substantially free of N (4-trifluoromethylphenyl) 2-cyano-3-hydroxycrotonamide, 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide and N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.
- 37. (currently amended) A pharmaceutical composition comprising the leflunomide of any one of claims 27 through 36 27-28 or 31-36.
- 38. (original) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 37.
- 39. (currently amended) A method of treating rheumatoid arthritis comprising administering to a patient in need of such treatment a therapeutically effective amount of the leflunomide of any one of claims 27 through 36 27-28 or 31-36.
- 40. (currently amended) A method of regulating cell proliferation comprising administering to a patient an amount of the leflunomide of any <u>one</u> of claims <del>27 through 36</del> <u>27-28 or 31-36</u> sufficient to inhibit cell proliferation.
- 41. (new) Leflunomide containing about 150 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 42. (new) The leflunomide of claim 41 containing about 100 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 43. (new) The leflunomide of claim 41 containing about 50 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 44. (new) The leflunomide of claim 41 containing about 10 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide.
- 45. (new) Leflunomide which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide.
- 46. (new) Leflunomide which is substantially free of N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.
- 47. (new) The leflunomide of claim 41, which is substantially free of 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide and N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide.